

EXHIBIT B

Docket No. 22956-214
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Shelby L. Cook et al.

Application No. 10/615,625

Filed: June 27, 2003

For: **BIOABSORBABLE SUTURE ANCHOR
SYSTEM FOR USE IN SMALL JOINTS**

Confirmation No. 9377

Art Unit: 3731

Examiner: Tuan Van Nguyen

I hereby certify that this correspondence is being sent via EFS-Web to: Mail Stop
Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-
1450, on the date shown below.

Dated: September 2, 2009

Signature: 

(Rory P. Pheiffer)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**Declaration of Shelby L. Cook, Jose E. Lizardi, Karl S. Reese, and Thomas A. Shepard
Pursuant to 37 C.F.R. § 1.131**

Dear Sir:

We, Shelby L. Cook, residing at 33 Fairway Lane, Foxboro, MA 02035, Jose E. Lizardi, residing at 3 Kayla Drive, Franklin, MA 02038, Karl S. Reese, residing at 764 Tremont Street, #5 Boston, MA 02118, and Thomas A. Shepard, residing at 5250 Greens Dairy Road, Raleigh, NC 27616, hereby declare as follows:

1. As co-inventors of the subject matter claimed in this patent application, we are familiar with the patent application and its claims, as well as the development of the claimed invention. We understand that an Office Action mailed March 30, 2009, rejects claims 1, 8, 9-13, 15, 16, and 19 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,320,701 of Haut et al. ("the Haut patent"), and furthermore, rejects claims 2, 3, 14, 17, and 18 pursuant to 35 U.S.C. §103(a) as being obvious over the Haut patent.

2. We understand that the Haut patent has a §102(e) date of June 2, 2003 (based on its filing date). We believe that the facts set forth below evidence that the invention claimed in this patent application was at least conceived prior to June 2, 2003, which is the earliest priority date that could possibly be claimed by the Haut patent.

3. Before June 2, 2003, at least two pages of drawings of the claimed invention were prepared, a redacted copy of which is attached hereto as Exhibit A. These drawings, which are dated (redacted) prior to June 2, 2003, illustrate the details of the invention as claimed in the independent claims, thus showing conception of the invention. In particular, the drawings illustrate a suture anchor for anchoring tissue to bone that is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in a suture channel of the anchor. An elongate body defined by a longitudinal axis of symmetry and having a first, leading end and a second, trailing end is illustrated at least in Figures A, Sections A-A, and the perspective views of pages 1 and 2, and Figure B of page 2. Two opposed surfaces between the first and second ends and a plurality of sidewalls extending between the two opposed surfaces is illustrated at least in the Figures A and the perspective views of pages 1 and 2. Figures A and the perspective views of pages 1 and 2 also illustrate a flared portion formed on the second end and extending from one of the sidewalls. The flared portion is adapted to engage and anchor into bone tissue. A suture channel formed in the elongate body for passage of a suture strand therethrough and extending between the two opposed surfaces is illustrated at least in Section A-A of page 1 and Section A-A and Figure B of page 2. As shown, the suture channel is oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and as shown in Figures A of pages 1 and 2, a centerline of the suture channel is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion.

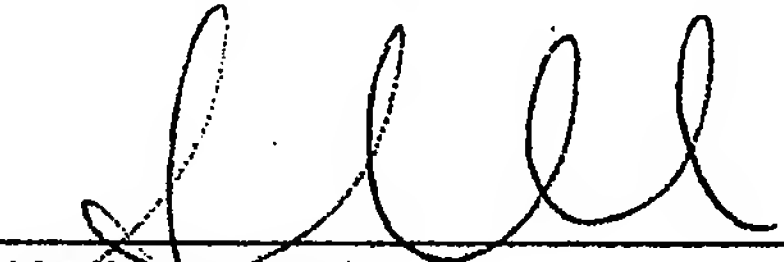
4. We were reasonably diligent in constructively reducing our invention to practice by filing a patent application on June 27, 2003, which is less than one month after the earliest priority date that could possibly be claimed by the Haut patent.

5. All of these acts relating to the conception and completion of this invention took place in the United States.

6. We further declare that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 14-Aug-2009


Shelby L. Cook

Date: _____

Jose E. Lizardi

Date: _____

Karl S. Reese

Date: _____

Thomas A. Shepard

1845139.1

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____

Shelby L. Cook

Date: Aug 17, 2009



Jose E. Lizardi

Date: _____

Karl S. Reese

Date: _____

Thomas A. Shepard

1845139.1

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____

Shelby L. Cook

Date: _____

Jose E. Lizardi

Date: 08/25/09



Karl S. Reese

Date: _____

Thomas A. Shepard

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____

Shelby L. Cook

Date: _____

Jose E. Lizardi

Date: _____

Karl S. Reese

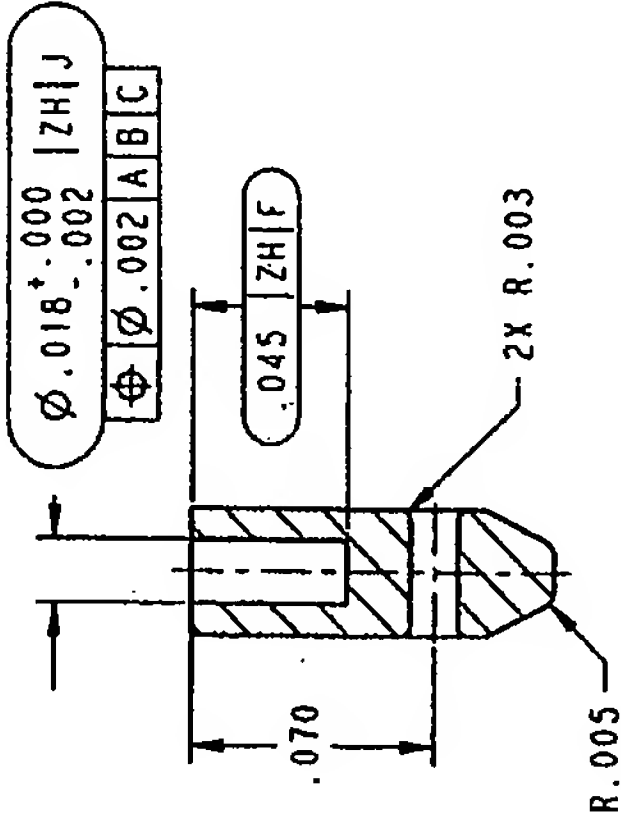
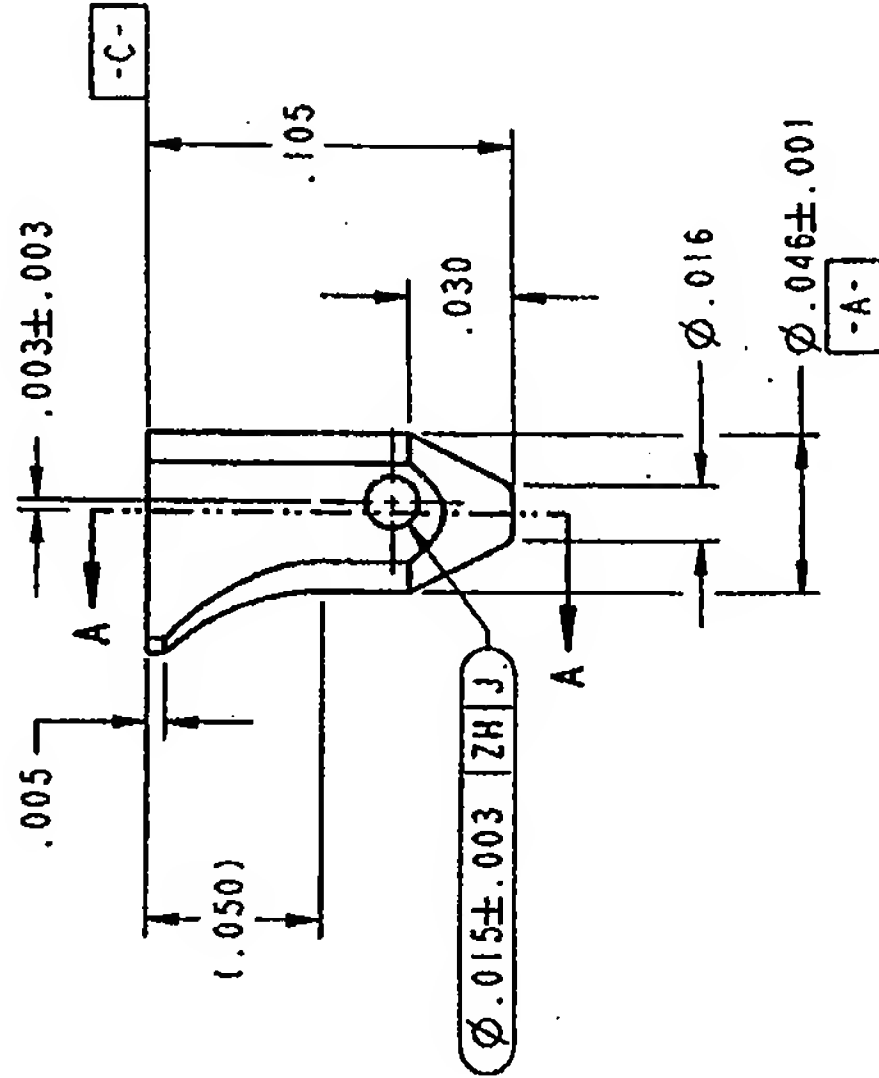
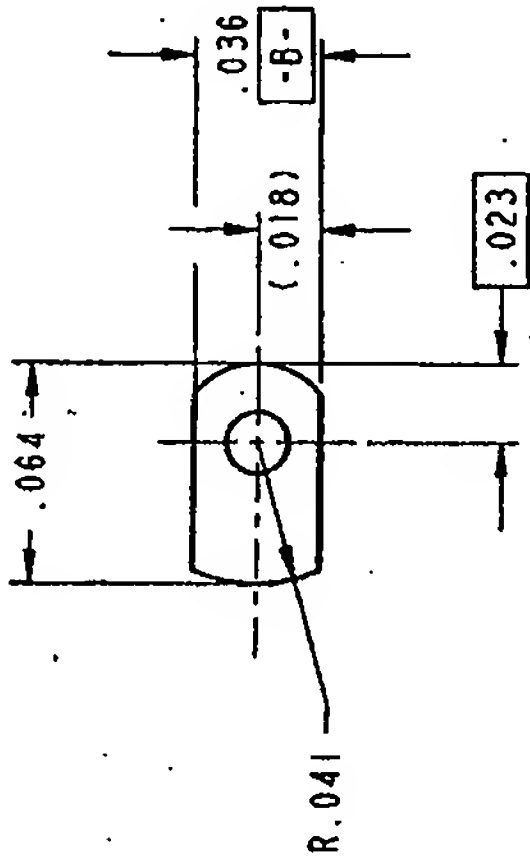
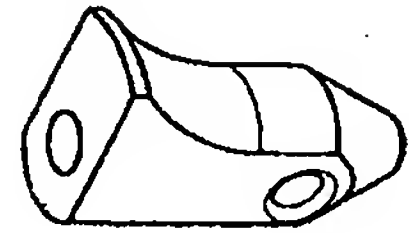
Date: 8/19/09



Thomas A. Shepard

Exhibit A

DO NOT SCALE THIS DRAWING



NOTES:
1. MATERIAL: REFERENCE TO P/N 105339 FOR MATERIAL SPECIFICATIONS
DYE PART #106297, D+C BLUE #6, RATIO PLA: DYE, 10,000:1
CERTIFICATION REQUIRED

2. FINISH: SPE/SPI #2 (REF).
- | | YB | U |
|--|----|---|
| 3. PARTING LINE .006 MAX MISMATCH ALLOWABLE IN X AXIS, .003 MAX MISMATCH ALLOWABLE IN Y AXIS. | YB | U |
| 4. PART TO BE FREE OF TOOL MARKS, SINKS, DIRT, FOREIGN MATTER AND MOLD RELEASE. | YB | U |
| 5. MATERIAL CERTIFICATION TO ACCOMPANY EACH LOT. USE VIRGIN MATERIAL ONLY (NO REGRIND ALLOWABLE). APPLIES ONLY TO OUTSIDE SUPPLIERS. | XA | W |
| 6. PARTS TO BE PACKAGED CLEAN, IN POLY BAGS. | YB | X |
| 7. .005 MAX GATE VESTIGE. | YB | X |
| 8. .005 MAX ALLOWABLE FLASH. | YB | X |

9. EJECTOR PIN MARKS TO BE FLUSH TO .0015 BELOW SURFACE.

10. INSPECT TO THE REQUIREMENTS OF SOP 201085.
GENERAL INCOMING INSPECTION PROCEDURE.

REVISION

REV	DESCRIPTION	R&D APPR	DATE	MFG APPR	DATE
1	DRAWING NUMBER WAS MR00010 REV 01	DB		LB	
2	DELETED NOTE 10 AND 11 MATERIAL WAS 106817 COMPOUND 15/85 B-TGP/L-PLA	RFW		LB	
3	ADDED GEOM TOL, UPDATED NOTE 1 NOTE 7 & 8 .064 WAS .061, R.041 WAS R.038, .105 WAS .130, .030 WAS .055, .005 WAS R.005, CORRECTED POSITION TOLERANCE	DMB		PMD	
4		SC		LB	

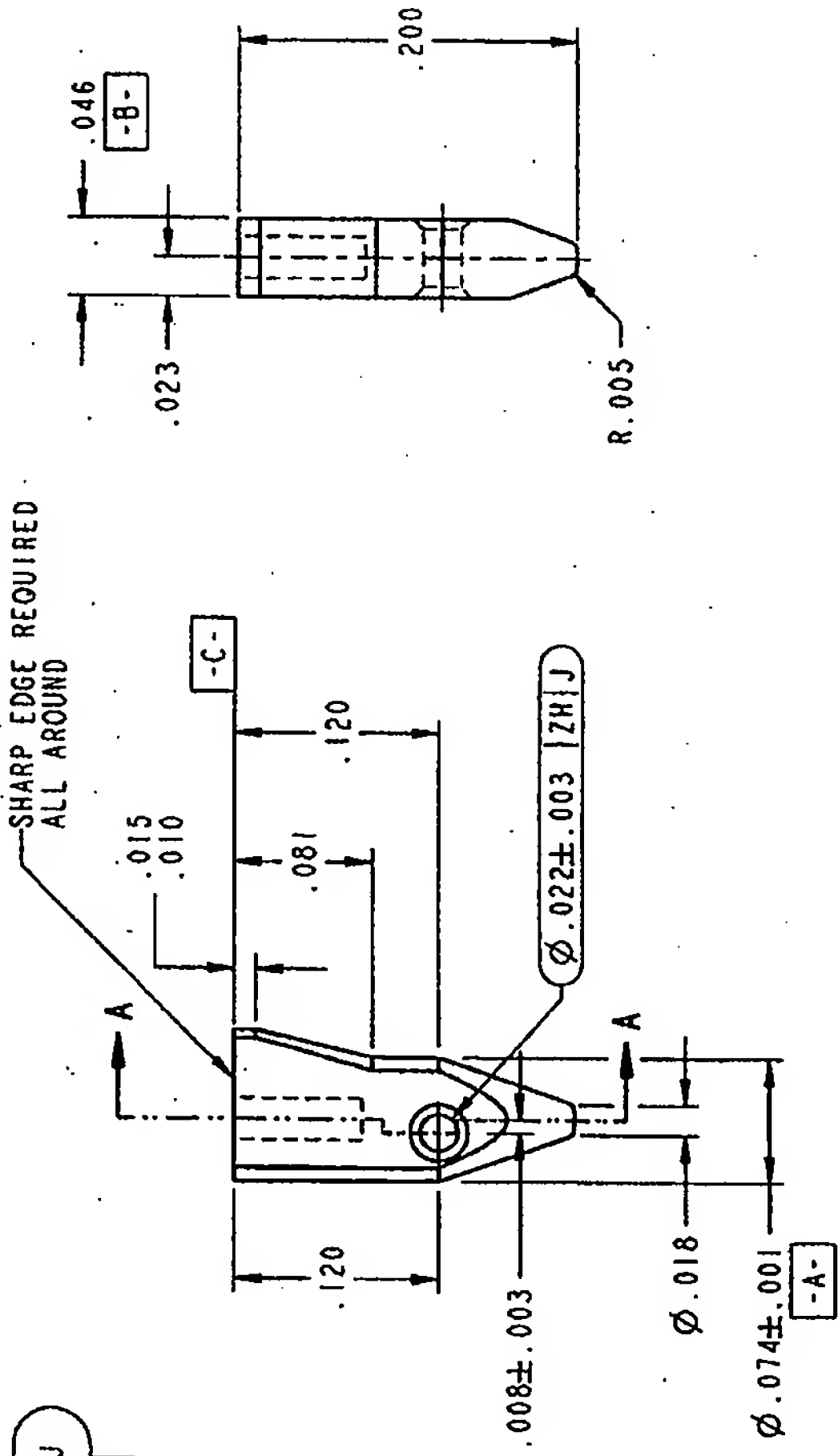
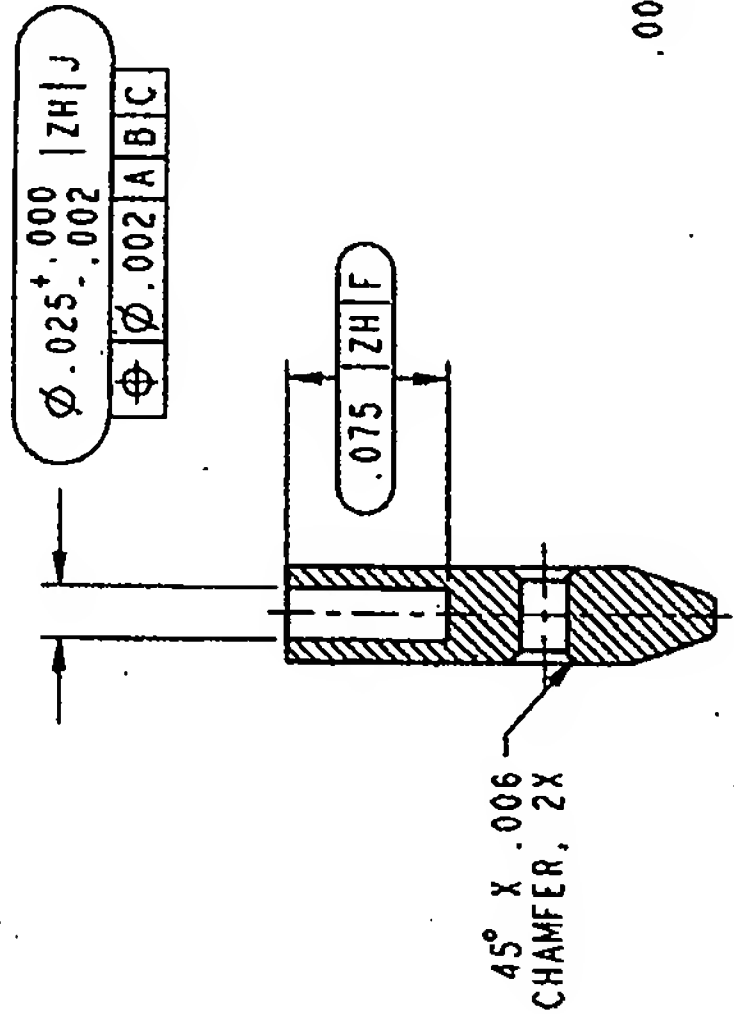
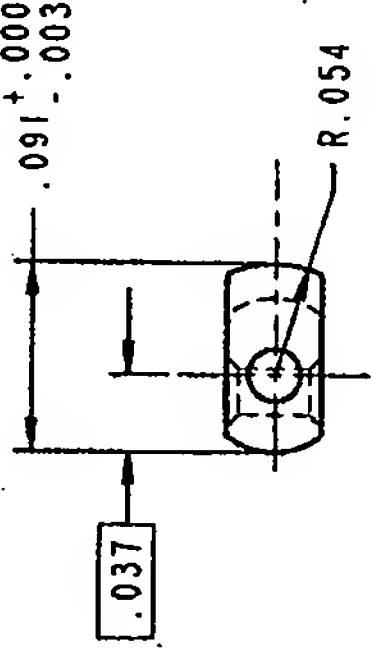
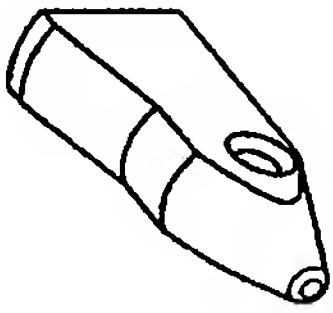
106947

QTY REQD	PART OR IDENT. NO.	DESCRIPTION	ITEM NO.
UNLESS OTHERWISE SPECIFIED: ANGULAR DIMENSIONS ± .1° SURFACE FINISHNESS 125 (3.2 µm) BREAK EDGES .01 (1.25mm) REMOVE ALL BURRS		MITIK WORLDWIDE 244 Yeardley Ave. Hartford, CT 06105 860-356-4835	
TOLERANCES ON DECIMALS		DRAWING TITLE	
FRACTIONS		S. DASILVA	
INCHES ±.1		DIRECTOR M. CAULDWELL	
MILLIMETERS ±.254		APPROVED D. BELLOLI	
THIRD ANGLE PROJECTION		PROJECT	
DIMENSIONS AND TOLERANCES ARE PER ANSI STD Y14.5		MATERIAL	
NEXT ASSY CATALOG NO.		SEE NOTES	
APPLICATION		SEE NOTES	
		SCALE 20:1	
		SHEET 1 OF 1	

MITIK

ANCHOR, ABSORBABLE.
MICRO (PLA)

DO NOT SCALE THIS DRAWING



SECTION A-A

- NOTES:
1. MATERIAL: REFERENCE TO P/N 105339 FOR MATERIAL SPECIFICATIONS
DYE PART # 106297, D+C BLUE #6, RATIO PLA: DYE, 10,000:1.
CERTIFICATION REQUIRED
 2. FINISH: SPE/SPI #2 (REF).
 3. PARTING LINE .006 MAX MISMATCH ALLOWABLE
IN X AXIS, .003 MAX MISMATCH ALLOWABLE IN Y AXIS.
 4. PART TO BE FREE OF TOOL MARKS, SINKS, DIRT,
FOREIGN MATTER AND MOLD RELEASE.
 5. MATERIAL CERTIFICATION TO ACCOMPANY EACH LOT, USE
VIRGIN MATERIAL ONLY (NO REGRIND ALLOWABLE). APPLIES
ONLY TO OUTSIDE SUPPLIERS.
 6. PARTS TO BE PACKAGED CLEAN, IN POLY BAGS.
 7. .005 MAX GATE VESTIGE.
 8. .005 MAX ALLOWABLE FLASH.
 9. EJECTOR PIN MARKS TO BE FLUSH TO .0015 BELOW SURFACE.
 10. INSPECT TO THE REQUIREMENTS OF SOP 201085.
GENERAL INCOMING INSPECTION PROCEDURE.

YB	U
YB	U
XA	W
YB	X
YB	X

REVISION

REV	DESCRIPTION	R&D APPR	DATE	MFG APPR	DATE
3	ADDED GEOM TOL. UPDATED NOTE 1, NOTE 7 & 8 .005 WAS .010, AND NOTE 9 .0015 WAS .004	DMB		PMD	
4	.087 ±.003 - .000 WAS .082, REMOVED .008 FLAT, ADDED SHARP EDGE NOTE 45° X .006 CHAMFER, 2X WAS 2X R.006	DMB		PMD	
5	ADDED .015/.010 STEP, ADDED R.077 REF. DIMENSION CORRECTED POSITION TOLERANCE	SC		LB	
6	.037 WAS .033, .091 WAS .087 .074 WAS .066, .081 WAS .065	SC		LB	
7	.008 ±.003 WAS .005 ±.003, .120 WAS .110	SC		PMD	

106950

QTY	PART OR IDENT. NO.	DESCRIPTION	ITEM NO.
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212851			
212852			
NEXT ASSY CATALOG NO.		APPLICATION	
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